

Message

From: David Fischer [david.fischer@bayer.com]
Sent: 8/15/2014 3:37:00 PM
To: Steeger, Thomas [Steeger.Thomas@epa.gov]
Subject: RE: Heads up about conference call with BCS on Monday

I appreciate your insight and will pass this advice on to the rest of the Sivanto team.

Dave

David L. Fischer, Ph.D.
Director, Pollinator Safety



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From: Steeger, Thomas [mailto:Steeger.Thomas@epa.gov]
Sent: Friday, August 15, 2014 11:04 AM
To: David Fischer
Subject: RE: Heads up about conference call with BCS on Monday

While the nonpublic EFED memo cites the Label Review Manual and is based on the acute oral toxicity of flupyradifurone to young adult bees, EFED has worked closely with the risk managers to devise language that is consistent with the overall weight-of-evidence available for the compound. It's my understanding that the actual proposed language for the Sivanto is not the standard language and would be advisory as opposed to compulsory.

It may come as a surprise to some folks that the risk managers and risk assessors working on flupyradifurone are familiar with the data, the risk assessment guidance (SETAC Pellston) and the Label Review Manual. The chemical team is also familiar with the intent to consider multiple lines of evidence associated with compound, as described in the guidance. It is not likely to be very productive to pull additional folks into the mix and/or to posture unnecessarily. It would be more productive to base discussions on the actual proposed label language within the context of what each of the three regulatory authorities will likely require.

From: David Fischer [mailto:david.fischer@bayer.com]
Sent: Friday, August 15, 2014 9:04 AM
To: Steeger, Thomas
Cc: Moriarty, Thomas
Subject: RE: Heads up about conference call with BCS on Monday

Tom S.,

I didn't mean to drag Tom M. into this if his presence discussions is inappropriate.

Regarding the EFED chapter, the technical review of the bee tests are not what we are concerned about. What we are concerned about is the following statement that is in the EFED memorandum (bottom of page 5 and top of page 6).

According to Chapter 8 of U.S. EPA's Label Review Manual, the following precautionary label language is recommended:

This product is highly toxic to bees and other pollinating insects exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees or other pollinating insects are visiting the treatment area.

I don't think this qualifies as measured and consistent with the data which clearly demonstrates applications during bloom to highly attractive crops and surrogate crops poses no unreasonable risk to bees.

I realize that what is going on is the application of archaic labeling criteria that have not been updated in concert with the risk assessment guidance. And I'm not actually sure if these criteria are even being applied correctly. The opening paragraph of Chapter 8 of the Label Review Manual states "the information contained in this section is based on the results of eight basic acute toxicity studies" with the applicable terrestrial invertebrate study being the "honey bee contact LD₅₀" (emphasis added), see below.

risk assessments performed by the Environmental Fate and Effects Division. Generally, the information contained in this section is based upon the results of eight basic acute toxicity studies performed on the technical grade of the active ingredient(s) in the formulation. These eight studies are: (1) avian oral LD₅₀ (with mallard *or* bobwhite quail), (2) avian dietary LC₅₀ (mallards), (3) avian dietary LC₅₀ (bobwhite quail), (4) freshwater fish LC₅₀ (rainbow trout), (5) freshwater fish LC₅₀ (bluegill sunfish), (6) acute LC₅₀ freshwater invertebrates (*Daphnia magna* or water flea), (7) honeybee contact LD₅₀, and (8) mammalian acute oral LD₅₀. For specific data requirements: *40 CFR Part 158*.

The honey bee contact LD₅₀ values for flupyradifurone when tested as the active ingredient and also as formulated end use products are greater than 11 µg/bee. Therefore, applying the criteria in the Label Review manual as they are actually written leads to a decision that there should be no label statement for bee toxicity.

BCS believes that decisions about label statements should be based on a full evaluation of the entire data package and the conclusions of the overall risk assessment. We believe the inclusion of the proposed label statement is contrary to the Agency's overall risk conclusion and decision to approve the use of this product on bee attractive crops during bloom.

Dave

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From: Steeger, Thomas [<mailto:Steeger.Thomas@epa.gov>]
Sent: Thursday, August 14, 2014 7:29 PM
To: David Fischer
Cc: Moriarty, Thomas
Subject: RE: Heads up about conference call with BCS on Monday

I believe the ecological risk assessment chapter is well measured and consistent with the data as well as the perspective of our regulatory counterparts who participated in the global review.

This is an RD action and while I appreciate Tom Moriarty's perspective, the risk management decision resides with Meredith Laws and Lois Rossi.

From: David Fischer <david.fischer@bayer.com>
Sent: Thursday, August 14, 2014 6:22 PM
To: Steeger, Thomas; Moriarty, Thomas
Subject: RE: Heads up about conference call with BCS on Monday

Here's the document Jamin just sent to Reuben and Meredith.

Dave

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From: Steeger, Thomas [<mailto:Steeger.Thomas@epa.gov>]
Sent: Thursday, August 14, 2014 5:21 PM
To: David Fischer; Moriarty, Thomas
Subject: RE: Heads up about conference call with BCS on Monday

My work schedule is from 5:30 am to 3:30 pm; since I typically working by 5 am, I take the liberty of leaving at 3:20 pm. If the meeting is starting at 4 pm, I will not be able to participate.

From: David Fischer <david.fischer@bayer.com>
Sent: Thursday, August 14, 2014 5:13 PM
To: Moriarty, Thomas; Steeger, Thomas
Subject: Heads up about conference call with BCS on Monday

Bayer is setting up teleconference with Meredith Laws, Reuben Baris and Lois Rossi (if available) next Monday at 4 pm and will also be requesting the you two attend. The purpose of the call is to discuss the Agency's proposed bee label statement in the Environmental Hazard section of the label for Sivanto (flupyradifurone, a.k.a. BYI 02960). A BCS position statement will be sent shortly to Meredith and Reuben outlining Bayer's position. I'll send you a copy tomorrow am just to be sure you have it.

I hope you can make the conference call on Monday.

Dave

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Director, Pollinator Safety



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